

123



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,476	02/08/2002	Young-Jin Chae	10933-017	8647
20583	7590	06/16/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 06/16/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/071,476	Applicant(s) CHAE, YOUNG-JIN	
	Examiner Konstantina Katcheves	Art Unit 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3-5 is/are allowed.
- 6) ☒ Claim(s) 6 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 3-6 and 8 are pending in the present application.

#### ***Response to Amendment***

Claims 6 and 8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* methods for expression, does not reasonably provide enablement for *in vivo* methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Any rejection not repeated herein is withdrawn.

#### ***Response to Arguments***

Claims 6 and 8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vitro* methods for expression, does not reasonably provide enablement for *in vivo* methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that: (1) the examples in the specification and the specification as a whole teach one of skill in the art how to use the claimed vector; (2) that the examiner is incorrect in asserting that the peptide vector does not overcome delivery; (3) that subsequent work by the inventors demonstrate that the peptide vector system works (Choi et al. Veterinary Immunology and Immunopathology Vol.103 223-233 2005, cited by Applicant); (4) that there is

Art Unit: 1636

no reason to believe that the GFP mRNA produced in the experiment did not produce active GFP; and (5) that Verma is not the standard for enablement.

Applicant's arguments that the examples in the specification and the specification as a whole teach one of skill in the art how to use the claimed vector and that the examiner is incorrect in asserting that the peptide vector does not overcome delivery are noted but not found persuasive. Applicant cites the examples showing GFP mRNA in support of the position that the present invention is enabled. Although Applicant cites an example wherein mRNA levels of GFP is measured using GFP specific primers, this example fails to provide enablement for at least three reasons. First, it does not overcome the problem of gene delivery to targeted cells. Second, it does not solve the problem of transient expression. Finally, it fails to show that the transferred protein was translated so that the desired protein would be expressed at sufficient levels to produce a desired function in the target cells. Additionally, Applicant's point that there is no evidence to believe that the GFP mRNA did not produce active GFP does accurately characterize the position of the examiner. The question raised is whether the protein is expressed at a sufficient level to and for a sustained period to have effect *in vivo*. The evidence that Applicant cites does not show that the GFP was expressed *in vivo* or if it was expressed in measurable amounts; no biofluorescence data is provided in the specification.

Applicant cites subsequent work by the inventors showing enablement of the claimed peptide vector in Choi et al. This work is noted however does not resolve the question of enablement. This article was published in 2005, long after the filing date of the present invention. According to the MPEP, "the 'amount of guidance or direction' refers to that information in the application, as originally filed, that teaches exactly how to make or use the

Art Unit: 1636

invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification.” See MPEP 2164.03. Because the art at the time the invention was filed supports the examiners position that the invention was unpredictable and that practicing the invention would require undue experimentation, more information must be “explicitly stated in the specification.” The specification fails to provide such explicit information to overcome the lack of enablement of the present invention.

Applicant also argues that Verma is not the standard for enablement. Applicant should note that the examiner cited the Wands factors in determining undue experimentation in the previous Office actions and that Verma was cited as evidence of unpredictability in the art which one of the Wands factors considered by the examiner. For the foregoing reasons, the instant claims stand rejected under the enablement requirement of 35 U.S.C. 112, first paragraph.

#### ***Allowable Subject Matter***

Claims 1, 3, 4, and 5 are allowable.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1636

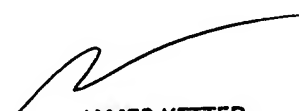
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



JAMES KETTER  
PRIMARY EXAMINER